



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON MA 02110

COPY MAILED Paper No.

AUG 27 2009

OFFICE OF PETITIONS

In re Patent No. 7,507,415 :
Arroyo et al. : DECISION DISMISSING
Application No. 10/715,868 : REQUEST FOR
Issue Date: March 24, 2009 : RECONSIDERATION OF
Filed: November 17, 2003 : PATENT TERM ADJUSTMENT
Attorney Docket No.: 06132/075002 : UNDER 37 CFR § 1.705(d)
Title: WEST NILE VIRUS VACCINE :

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 705," filed on May 26, 2009, which is being treated as a petition pursuant to 37 CFR § 1.705(d), requesting that the patent term adjustment determination for the above-identified patent be changed from four hundred and four (404) to six hundred and seventy-seven (677) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On March 24, 2009, the application matured into U.S. Patent No. 7,507,415, with a revised patent term adjustment of 404 days. On May 26, 2009, patentees timely submitted this request for reconsideration of patent term adjustment within two months of the issue date of the patent. Patentees request 495 days of additional patent term adjustment in accordance with the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the non-overlapping between the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), and the period of adjustment due to examination delays, pursuant to 37 CFR §§ 1.702(a)(1), (a)(2), and (a)(4) is 348 days as these periods do not occur on the same day. Accordingly, patentees contend that "the Office delay associated with the '415 patent is 228 days (A delay) +

495 days (B delay) + 120 days (A delay) = 843 days, while the applicant delay is 166 days (as calculated by the Office).¹ Thus, patentee asserts an entitlement to a patent term adjustment under 37 C.F.R. § 1.703 of 677 days.

Pursuant to 35 U.S.C. 154(b)(1)(B), the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed. As acknowledged by patentees, this period does not include any time consumed by continued examination of the application requested by the applicant under section 132(b). Thus, the relevant period in considering this overlap ends with applicant's filing of the request for continued examination (RCE) pursuant to section 132(b). Further, the period for over three-year pendency does not include any period of adjustment which overlaps with the period of adjustment for Office delay accorded pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a).

The Office agrees that the application was pending 3 years and 495 days after its filing date, as of the filing of the request for continued examination (RCE) on March 26, 2008. Moreover, as of the filing of the RCE, 296 days of adjustment for Office delay had been accorded pursuant to 35 U.S.C. 154(b)(1)(A) and §§ 1.702(a)(1) and (a)(2).² At issue is whether the period of adjustment of 495 days attributable to the Office taking in excess of three years to issue the patent overlaps with the adjustment of 296 days attributable to the Office's failures to issue a first Office action no later than fourteen months after the application filing date and to respond to the response to the non-final Office action of June 19, 2007 within four months. The Office is of the position that the 495 days do overlap and thus, entry of the 495 days for over three-year pendency is not permitted. Accordingly, at issuance, the Office properly entered 199 (495 - 296) additional days of patent term adjustment for the Office taking in excess of 3 years to issue the patent, and the Office calculated the patent term adjustment as 371 (296 + 75) + 199 - 166 = 404 days.

¹ Petition, page 6.

² The other 75 days of adjustment were accorded subsequent to the filing of the RCE and thus, are not considered in determining overlap with the 3 year period which ends with the filing of the RCE.

This calculation of the patent term adjustment has been reconsidered and is affirmed. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term*

Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (June 15, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

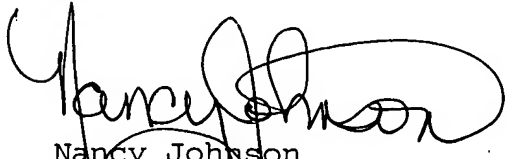
The Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A). The period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames.

In this instance, there is an excluded period for the filing of a request for continued examination (RCE). Thus, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period beginning on the date of filing of the application, November 17, 2003 and ending on the date of filing of the request for continued examination, March 26, 2008. 296 days of adjustment for Office delay were accorded prior to the filing of the RCE. The 495 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 296 days attributable to grounds specified in §§ 1.702(a)(1) and (a)(2). Entry of both periods is neither permitted nor warranted.

In view thereof, the Office affirms that the revised determination of patent term adjustment at the time of the issuance of the patent is 404 days (371 + 199 - 166).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Paul Shanoski, Senior Attorney, at (571) 272-3225.

A handwritten signature in black ink, appearing to read "Nancy Johnson". The signature is fluid and cursive, with a large loop at the end.

Nancy Johnson
Senior Petitions Attorney
Office of Petitions